

CLAIMS

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1. A taste masked formulation which rapidly releases in the stomach of a patient comprising:

A drug containing core;

5 A taste masking layer composed of a material which is generally insoluble in saliva at a neutral to basic pH and completely soluble in saliva at a pH of less than about 6.5; and

A spacing layer surrounding said core and substantially completely sequestering said core from said taste
10 masking layer; said taste masking layer preventing exposure of said spacing layer in the mouth of a patient for a period of at least about 20 seconds after being placed into the mouth.

2. The formulation of claim 1 wherein said taste masking layer is capable of rapidly exposing said spacing layer when in
15 the stomach of a patient.

3. The formulation of claim 1 wherein said spacing layer is capable of rapidly exposing the contents of said core when said spacing layer is exposed in the stomach of a patient.

4. The formulation of claim 1 wherein said spacing layer
20 is a controlled release material which allows for drug dissolution from the core in a desired release pattern including, but not limited to steady, pulsatile, delayed or targeted.

5. The formulation of claim 1 wherein said drug is a
25 pharmaceutically active material, a vitamin, a mineral, a nutritional supplement and mixtures thereof.

6. The formulation of claim 1 wherein said spacing layer increases the weight of the core by between about 5 and about 100 percent by weight.

30 7. The formulation of claim 6 wherein said spacing layer increases the weight of the core by between about 20 and about 50 percent by weight.

8. The formulation of claim 1 wherein said spacing layer has a thickness of between about 5 and about 75 microns.

9. The formulation of claim 8 wherein said spacing layer has a thickness of between about 5 and about 30 microns.

5 10. The formulation of claim 1 wherein said taste masking layer increases the weight of the core by between about 5 and about 100 percent by weight.

10 11. The formulation of claim 10 wherein said taste masking layer increases the weight of the core by between about 20 and about 70 percent by weight.

12. The formulation of claim 1 wherein said taste masking taste masking layer has a thickness of between about 5 and about 75 microns.

15 13. The formulation of claim 12 wherein said taste masking layer has a thickness of between about 5 and about 30 microns.

14. A dosage form intended for direct oral administration, comprising:

20 an effective amount of at least one drug, said drug present in the cores of coated particles, said cores including a taste masking layer composed of a material which is generally insoluble in saliva at a neutral to basic pH and completely soluble in saliva at a pH of less than about 6.5; and

25 a spacing layer surrounding said core and substantially completely sequestering said core from said taste masking layer; said taste masking layer preventing exposure of said spacing layer in the mouth of a patient for a period of at least about 20 seconds after being placed into the mouth; and

30 at least one pharmaceutically acceptable excipient provided in an amount of between greater than zero and less than 100%, based on the weight of the finished dosage form.

15. The dosage form of claim 14 wherein said coated particles are present in an amount of between greater than zero

and about 95% by weight based on the weight of the finished dosage forms.

16. The dosage form of claim 15 wherein said coated particles are present in an amount of between greater than zero
5 and about 75% by weight based on the weight of the finished dosage forms.

17. The dosage form of claim 14 further comprising a disintegrant wherein the amount of said disintegrant and said excipient are between greater than zero and about 95% by weight
10 based on the weight of the finished dosage forms.

18. The dosage form of claim 17 wherein said disintegrant and said excipient are present in an amount of between greater than zero and about 75% by weight based on the weight of the finished dosage forms.

15 19. The dosage form of claim 14 wherein said taste masking layer is capable of rapidly exposing said spacing layer when in the stomach of a patient

20 20. The dosage form of claim 14 wherein said spacing layer is capable of rapidly exposing the contents of said core when said spacing layer is exposed in the stomach of a patient.

21. The dosage form of claim 14 wherein said spacing layer is a controlled release material which allows for drug dissolution from the core in a desired release pattern including, but not limited to steady, pulsatile, delayed or
25 targeted.

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